

NOV 25 2005

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 23-R-0107

FORM APPROVED  
OMB NO. 0579-0036

CUSTOMER NUMBER: 366

**ANNUAL REPORT OF RESEARCH FACILITY**  
( TYPE OR PRINT )

Calvert Laboratories Inc  
Scott Technology Park  
100 Discovery Drive  
Olyphant, PA 18447

Telephone: (570) -586-2411

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS ( Sites ) - See Attached Listing

**REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report )	F. TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	52	577	100	9	686
5. Cats	0	0	0	0	0
6. Guinea Pigs	20	746	50	0	796
7. Hamsters	0	114	0	0	114
8. Rabbits	132	1,566	35	12	1,613
9. Non-human Primates	8	154	11	0	165
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					

**ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )

DATE SIGNED

(b)(6), (b)(7)(c)

11/22/05

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Certificate Number: 23-R-0107

Customer Number: 366

**Exercise Exemptions - Dog**

Twenty one (21) dogs were exempted from exercise for 45 days each to allow for recovery from surgery to install telemetry implants.

**Pair Housing Exemptions - Primate**

Four (4) primates were exempted from pair housing for 365 days each due their aggressive nature and resultant incompatibility.

Forty eight (48) primates were rotated between pair housing & single housing for 279 days each.

Eleven (9) primates were exempted from pair housing for 14 days each to allow for recovery from a single subretinal injection.

Two (2) primates were exempted from pair housing for 14 days each to allow for recovery from a single intravitreal injection.

Certificate Number : 23-R-0107

Customer Number: 366

### **Column E Explanation**

Dogs – One (1) animal in subchronic toxicity test experienced emesis, decreased activity and decreased body temperature. The animal was humanely euthanized. The use of pharmaceuticals to alleviate pain or distress may have interfered with the compound being tested, thereby invalidating the data collected which would in turn require repeat testing and increase the number of animals utilized. The conduct of a subchronic toxicity study in a non-rodent species is a requirement of worldwide regulatory agencies. (1, 2, 3) (Per Organization for Economic Co-Operation and Development (OECD) Guideline 401)

Dogs – Eight (8) animals in a subchronic toxicity test experienced emesis which did not subside when dosing was stopped. The animals were humanely euthanized. The use of pharmaceuticals to alleviate pain or distress may have interfered with the compound being tested, thereby invalidating the data collected which would in turn require repeat testing and increase the number of animals utilized. The conduct of a subchronic toxicity study in a non-rodent species is a requirement of worldwide regulatory agencies. (1, 2, 3) (Per Organization for Economic Co-Operation and Development (OECD) Guideline 401)

Rabbits – Eleven (11) animals were used in skin toxicity testing. The animals developed focal skin necrosis and were humanely euthanized. The use of pharmaceuticals to alleviate pain or distress may have interfered with the compound being tested thereby invalidating the data collected which in turn would require repeat testing and increase the number of animals utilized.  
(Per Organization for Economic Co-Operation and Development (OECD) Guideline 404)

Rabbits - One (1) animal in a subchronic toxicity test was found to have elevated intraocular pressure. The animal was humanely euthanized. The use of pharmaceuticals to alleviate pain or distress may have interfered with the compound being tested, thereby invalidating the data collected which would in turn require repeat testing and increase the number of animals utilized.  
(Per Organization for Economic Co-Operation and Development Guideline 404)

### **REFERENCES:**

1. Gad, Shayne c. (ed.). (1995). *Safety Assessment for Pharmaceuticals*. Van Nostrand Reinhold, New York. Pp.111-128.
- 2) Speid, L.H., Lumley, C.E. and Walker, S.R. (1990). Harmonization of Guidelines for Toxicity Testing of Pharmaceuticals. *Regulatory Toxicology and Pharmacology*, 12: 179-211.
- 3) Study conducted under GLPs for FDA/OECD preclinical drug development and submission to regulatory agencies.